For Consideration
Comments by the United States of America on Texts Submitted for Consideration
International Animal Health Code Committee
January 2002 Report

Appendix X.X.X
Guidelines for Assessing the BSE Risk of a Cattle Population

This document provides a good outline of the extent and type of information needed to assess the BSE risk. However, those specific points are somewhat self-explanatory in the actual Code Chapter. Therefore, do we really need this Appendix to describe, for example, the documentation needed to outline the number of animals imported? Just to continue with this example, the more critical part is how to assess the release risk presented by these animals. No guidance is given on this point. In addition, no guidance is given on how to fit all of these points together to come up with an overall assessment of risk. This is where international standards are needed – how to fit all of this together, not simply how to identify and document the data necessary.

The risk analysis as addressed here is only one of several criteria in Article 2.3.13.1 that are necessary to determine the BSE status of a country or zone. If this exercise is to be useful, this Appendix should provide guidelines as to how to determine the BSE status, not simply how to identify data for a risk assessment.

Specific points to note:

(1) Remove all references to embryos/oocytes – the recently completed research on embryos has documented that properly washed bovine embryos present minimal risk of transmission of BSE.

(2) Article X.X.X.2 – the first two statements in the 'Assumptions' section reference meat-and-bone meal as playing "the major role in BSE transmission." While this is correct, it is more accurate to state that INFECTED meat-and-bone meal plays the major role in transmission – it's not just the consumption of MBM that causes disease. Therefore, these two statements should read as follows (changes in italics):
   a. That the consumption by bovines of *infected* meat-and-bone meal or greaves of ruminant origin plays the major role in BSE transmission.
   b. That commercially-available animal protein products used in animal feeds may contain *infected* meat-and-bone meal or greaves of ruminant origin.

(3) Article X.X.X.2 – The second point on rationale reads as follows: "If cattle have been fed animal protein products potentially containing MBM or greaves of ruminant origin within the last 8 years, then the extent to which this poses a risk needs to be assessed." The following points simply describe the documentation

needed to outline the situation – the issue of identifying the extent to which this poses a risk is not addressed. Guidelines as to how to identify whether a risk is present, and if so, the extent of this risk, need to be developed.

(4) Article X.X.X.4 makes the following statement: "Countries which have imported cattle from BSE-infected countries are more likely to experience BSE." While this is correct, it is misleading. First of all, how do we know that it is the import of cattle rather than the import of infected MBM which has led to additional countries being infected? If this statement is to be included, it should be qualified in some way – such as "countries which have imported cattle or MBM from BSE-infected countries are more likely to experience BSE."

(5) In general, in this same article, many references are made to "animals" with no further definition of species. If taken literally, this could mean information must be provided about the importation of horses, swine, perhaps even poultry – none of which is relevant for purposes of this risk assessment. This should be clarified and refer only to ruminants, not animals.

(6) This same article includes the following statement: "Risk is proportional to volume of imports (Article 1.3.2.3)." Similar to other comments, this statement is correct, but it is misleading and leaves out quite a bit of information. Yes, the volume of imports is an important point in calculating the risk, but there are other equally critical points – the time of importation, use and disposition of the carcass, the type of ruminant imported, etc. Although these other points are mentioned elsewhere, they should also be referenced in this point in some way

(7) Again, this article provides a list of points that influence the release risk. Yet no guidelines are given to clarify how to factor all of these together and calculate the release risk.

(8) Article X.X.X.6 includes the following rationale: "If scrapie is present, the risk of endogenously generated release of BSE, originating from scrapie, will be less where the ratio of sheep to cattle is lower." What is the definition of "endogenously generated release of BSE"? Is the assumption here that scrapie was the original source of BSE? If that is the assumption, that needs to be clearly laid out. In addition, further information should be provided to back up the apparent assumption that scrapie jumped the species barrier and became BSE in more than one country – otherwise why are we talking about "endogenously generated release of BSE?" And where specifically did that theoretically happen besides the UK?

(9) Article X.X.X.7 – One of the assumptions states that "Pre-clinical TSE cannot be detected by any method …" This is not entirely accurate. The abnormal form of the prion protein may be present and detected in the brain stem of infected animals for up to 3 months before overt clinical signs are demonstrated. This

statement should be qualified in some manner, either by defining the time frame or stating that it is difficult to pick up pre-clinical cases.

(10) This same article includes a rationale that "Where MBM is utilized in the production of any animal feeds, the risk of cross contamination exists." This is too broad. Through the use of dedicated facilities and transport, cross contamination can be controlled. This statement should be modified such that it reads "… the risk of cross contamination may exist."

(11) Article X.X.X.8 gets to the real point, yet provides no guidance on calculating any of these risks. It states that the overall risk is proportional to exposure to infectivity and recycling. This is probably already understood and this additional explanation does not clarify things significantly. The issue is how to put all of these risk factors together in an accurate, realistic manner to calculate the risk – and this issue is not addressed at all in this document. In addition, the following language from the existing chapter is used " … demonstrated that appropriate measures have been taken to manage any risks identified." Guidelines on what are appropriate measures for the identified risks would be helpful in this document.